UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,270	10/02/2003	Hiroki Sakakibara	7412/80657	3446

42798 7590 09/26/2006

FITCH, EVEN, TABIN & FLANNERY
P. O. BOX 65973
WASHINGTON, DC 20035

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,270	SAKAKIBARA ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 03/05/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ritter et al., (US 6,086,863).

2. Ritter discloses a therapeutic compositions of microspheres for application to wound and/or lesions for accelerating wound healing and muscle regeneration. The therapeutic composition further contains pharmacologic agents or biologics that accelerate the wound healing process (see abstract). Essentially, all wound healing involves the repair or replacement of damaged tissues including but not limited to skin, muscle, neurologic tissues, bone, soft tissue, internal organs or vascular tissue (see column 1, lines 19-25, which would encompass "Vascularization therapy" as claimed). Most of basic research in angiogenesis has concentrated on the various steps involved in blood vessel growth and in identifying molecules that either enhance or inhibit such processes. The therapeutic composition includes genetically engineered stromal cells (e.g. fibroblasts with or without other cells and/or elements found in loose connective tissue taken from the subject, including but not limited to, endothelial cells, pericytes, macrophages, monocytes, plasma cells, mast cells, adipocytes, etc,) which express a gene product beneficial for successful and/or improved wound healing process. It is known that during angiogenesis vascular remodeling and maturation occurs, leading to an upsurge of interest in the pericyte, a cell of key

importance in such a pathways (see column 10, lines 2-12+). The therapeutic composition includes microspheres and one or more of agents selected from the group consisting of anti-inflammatory, antibiotic, antiseptic, antifungal, analgesic, astringent agent and collagen for healing the injured tissue (see column 4, lines 12-16). The therapeutic composition comprising microspheres discloses induced an initial increase in creatine phosphokinase activity of cultured myoblasts, which is correlated with biochemical maturation of myogenic cells (see column 15, lines 66-67 and column 16, lines 1-47+). These disclosures render the claims anticipated.

3. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al., (US 5,602,183 here after '183).

4. The '183 patent discloses a therapeutic dermotological wound healing composition comprising a buffering agent, an anti-inflammatory agent and a wound healing composition required for the repair of cellular membranes and resuscitation of mammalian cells (see column c 1, lines 15-32). The '183 patent also discloses wound healing process whereby the injured tissue is repaired, specialized tissue is regenerated and new connective or granulation tissue and blood vessels are formed. Wound healing compositions can increase the resuscitation rate of injured mammalian cells and the proliferation rate of new mammalian cells to replace dead cells (see column 1, lines 46-57 and column 8, lines 21-35). The '183 patent also discloses the dermatological-wound healing compositions contain a therapeutically effective amount of topical antiseptic to

further reduce the duration and severity of healing (see column 8, lines 17-20). The '183 patent also discloses the therapeutic wound healing composition being used in ingestible products to protect and increase the resuscitation rate of erosions, stomach ulcers, and hemorrhages in the gastric mucosa and thereof (see column 22, lines 11-30). The wound healing composition may also be used in tissue culture media and organ transplant media to prevent and reduce injury to mammalian cells and increase the resuscitation rate of injured mammalian cells (see column 41, lines 22-30). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Annie et al (The FASEB Journal 1998, 12:1331). In view of Vyakarnam et al., (US 2001/0033857).

7. Claims 1-9 are drawn to method of treatment comprising vascularizttion therapy to regenerate blood vessels.

8. The Annie publication discloses a process of endothelial cell production and coculture of various cell types to regenerate tissue and blood vessels. Annie also discloses a method of developing a vascular like network inside tissue-engineered skin to improve graft vascularization.

9. The Annie publication fails to teach specifically the treatment of fabricated collagen biopolymer with antiseptic solution to remove contamination and bacteria during the process of vascularization.

10. The Vyakarnam publication discloses the use of porous biocompatible bioabsorbable gradient foam comprising microstructure as a template for tissue regeneration, repair or augmentation (see Para 0001).

11. The Vyakarnam publication fails to teach the use of this biocompatible bioabsorbable foam in carbonated water at warm temperatures for the repair or regeneration of tissue. The prior art provides various methods of vascularization or angiogenesis process, which involves the formation of new blood vessels from pre-existing vessel bed and wound healing in diseased or injured tissues. The adult cutaneous vasculature is usually quiescent but retains the ability to initiate a rapid physiological (e.g. hair cycle, wound healing) or pathological angiogenic response if the balance between endogenous inhibitors and stimuli is altered.

12. It would have been obvious to one of ordinary skill in the art to modify the biopolymers of Annie for endothelial cell proliferation, because it is known in the art that contamination of the polymer with bacteria and other foreign particles will

degenerate endothelial cells and consequently tissue regeneration process of tissue and blood vessels.

13. It would have been obvious to one of ordinary skill in the art to modify the biopolymer of Vyakarnam by co culturing the biocompatible bioabsorbable foam in an aqueous carbonated media at desired temperature for regeneration of blood vessels and tissue from pre-existing vessel bed and wound healing in diseased or injured tissues, because it is known in the art that growth of new capillary blood vessels occurs during wound healing, development of the corpus luteum, and formation of blood vessel collaterals.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER